Drug Registration Readiness Checklist

India (CDSCO and State Licensing Authorities). Collect these before the pathway assessment starts.

Product

- ☐ Active ingredient, dosage form, strength, route
- ☐ Proposed indication, population and claims
- ☐ Chemical entity, biological, vaccine, phytopharmaceutical or FDC

Regulatory history

- ☐ Countries where approved, with dates and approved indications
- ☐ Indian approval status of the molecule; date of first Indian approval
- ☐ New drug status under NDCT Rule 2(1)(w); four-year window open or closed
- ☐ Previous CDSCO submissions, queries, SEC minutes or rejections

Manufacturing

- ☐ API manufacturer and site
- ☐ Finished product manufacturer and site
- ☐ GMP certificates and inspection history
- ☐ Indian applicant (agent or subsidiary) and its wholesale license (Form 20B/21B)

Quality (CMC)

- ☐ Composition and specifications
- ☐ Analytical methods and validation
- ☐ Stability data, including Zone IVb (30 °C / 75% RH)
- ☐ Batch records and certificates of analysis
- ☐ Container closure and packaging

Non-clinical and clinical

- ☐ Non-clinical package
- ☐ Clinical development history
- ☐ Clinical study reports and statistical analysis plans
- ☐ Integrated safety and efficacy summaries
- ☐ Post-marketing experience in reference countries

Regulatory plan

- ☐ Proposed Indian classification and pathway
- ☐ Import or manufacturing model
- ☐ Local trial position: Rule 101 waiver category, bridging study or full trial
- ☐ Forms, authorities and order of filing
- ☐ Identified documentation gaps
- ☐ Post-approval plan: PSUR cadence, pharmacovigilance, variations

CDSCO and State Forms: Quick Reference

Which permission, which authority, which form. Tick the ones your product needs.

Permission	Authority	Apply	Grant	
Clinical trial permission	CDSCO (CLA)	CT-04	CT-06	☐
Bioavailability / bioequivalence study	CDSCO (CLA)	CT-05	CT-07	☐
Manufacture of new drug for clinical trial / test and analysis	CDSCO (CLA)	CT-10	CT-11	☐
Import of new drug for sale	CDSCO (CLA)	CT-18	CT-19 (API) / CT-20 (formulation)	☐
Manufacture of new drug for sale	CDSCO (CLA)	CT-21	CT-22 (API) / CT-23 (formulation)	☐
Registration of overseas site and its drugs	CDSCO	Form 40	Form 41 (valid 3 years)	☐
Import license for registered drugs	CDSCO	Form 8 (8A for testing)	Form 10 (10A for testing)	☐
Manufacturing license, drugs outside Schedule C / C(1)	State Licensing Authority	Form 24	Form 25	☐
Manufacturing license, Schedule C / C(1) drugs	State Licensing Authority	Form 27	Form 28	☐
Wholesale license held by the Indian importer	State Licensing Authority	Form 19	Form 20B and 21B	☐

Published CDSCO processing targets

- CT-04 to CT-06: 90 working days; 30 working days with deemed approval for a drug discovered or developed in India
- New drug, SND, FDC and IND applications with SEC review: 90 working days
- Form 40 to Form 41: 270 working days (Citizen Charter); Form 8 to Form 10: 45 working days
- PSUR after approval: every 6 months for 2 years, then annually for 2 years (NDCT Rules)

Notes and identified gaps